

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

**ALLERGAN, INC.,
Plaintiff,**

v.

**TEVA PHARMACEUTICALS USA, INC.,
AKORN, INC., MYLAN
PHARMACEUTICALS INC., and MYLAN
INC.,
Defendants.**

**Civil Action No. 2:15-cv-1455-WCB LEAD
JURY TRIAL DEMANDED**

**ALLERGAN, INC.,
Plaintiff,**

v.

**INNOPHARMA, INC.,
Defendant.**

Civil Action No. 2:15-cv-1504-WCB

**ALLERGAN, INC.,
Plaintiff,**

v.

**FAMY CARE LIMITED,
Defendant.**

Civil Action No. 2:16-cv-0401-WCB

DEFENDANTS' RESPONSIVE CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

	<u>Page</u>
I. Introduction.....	1
II. Dry Eye, Dry Eye Disease, Dry Eye Syndrome, Keratoconjunctivitis Sicca	2
A. The Dry Eye Terms Are Used Colloquially and Refer to a Number of Different Causes.....	3
B. The Intrinsic Record Provides No Clarification as to the Meaning or Causes of Dry Eye, Dry Eye Disease, Dry Eye Syndrome or KCS.....	5
C. Allergan Erroneously Relies on Prior Art References Not Incorporated By Reference To Support its Proposed Construction	7
D. Allergan’s Proposed Constructions Fail Because All Signs And Symptoms of “Dry Eye” And “KCS” Are Not Ultimately Caused by Inflammation	8
E. Allergan’s Proposed Constructions are Inconsistent with Its Other Proposals, the Intrinsic Record, and the Presumption of Claim Differentiation.....	9
III. Efficacy	10
A. Allergan’s Proposed Constructions Fail to Identify the “Underlying Disease” to Be Treated.....	11
B. The Patents Fail to Disclose the Particular Methods Used to Determine Whether the Metes and Bounds of the Efficacy Claims Have Been Met.....	12
IV. Enhancing and Restoring	13
V. Second Topical Ophthalmic Emulsion	16
VI. About.....	18
A. “About” Should be Construed to Mean Precisely the Amount Recited or, Alternatively, is Indefinite	18
1. Neither the Claims nor the Specification Clarify the Scope of “About”	19
2. The Prosecution Histories Limit “About” to the Precise Amounts Claimed	19
3. Allergan’s Cases On “About” Do Not Apply	24
B. In the Alternative, the Term “About” is Indefinite	25
VII. Administering	27
VIII. Cyclosporin A is the Only Peptide Present.....	29
IX. Conclusion	30

TABLE OF AUTHORITIES

Page(s)

CASES

<i>Alcon Res. Ltd. v. Barr Labs, Inc.</i> , 745 F.3d 1180 (Fed. Cir. 2014).....	17
<i>Allergan Inc. v. Sandoz, Inc. et al.</i> , No. 6:11-cv-441, Dkt. No. 118, 2013 WL 139350 (E.D. Tex. Jan. 10, 2013).....	25
<i>Amgen, Inc. v. Chugai Pharm. Co.</i> , 927 F.2d 1200 (Fed. Cir. 1991)	25, 26, 27
<i>Andrulis Pharm. Corp. v. Celgene Corp.</i> , C.A. No. 13-1644-RGA, 2015 WL 3978578 (D. Del. Jun. 26, 2015), <i>aff'd</i> No. 2015-1962, 2016 WL 3755929 (Fed. Cir. July 14, 2016).....	11, 13
<i>Andrulis Pharms. v. Celgene Corp.</i> , No. 2015-1962, 2016 WL 3755929 (Fed. Cir. July 14, 2016).....	29
<i>AstraZeneca AB v. Hanmi USA, Inc.</i> , No. CIV.A. 11-760 JAP, 2012 WL 6203602 (D.N.J. Dec. 12, 2012), <i>aff'd</i> , 554 F. App'x 912 (Fed. Cir. 2013)	29
<i>Biopolymer Eng'g, Inc. v. Immunocorp</i> , No. CIV. 05-2972 JNE/JJG, 2007 WL 4562592, at *10, 12 (D. Minn. Dec. 21, 2007).....	24
<i>BJ Servs. Co. v. Halliburton Energy Servs.</i> , 338 F.3d 1368 (Fed. Cir. 2003)	25
<i>Cayenne Medical, Inc. v. Medshape, Inc.</i> , No. 2:14-cv-0451, 2016 WL 2606983 (D. Ariz. May 6, 2016).....	25
<i>Dow Chemical Co. v. Nova Chemicals Corp. (Can.)</i> , 803 F.3d 620 (Fed. Cir. 2015)	2, 5
<i>Exxon Research & Eng'g Co. v. U.S.</i> , 265 F.3d 1371 (Fed Cir. 2001)	25
<i>Fairfield Industries, Inc. v. Wireless Seismic, Inc.</i> , 4:14-CV-2972, 2015 WL 1034275 (S.D. Tex. March 10, 2015).....	26
<i>Fenner Inc., Ltd. v. Microsoft Corp.</i> , No. 6:07 CV 8, 2008 WL 3981838 (E.D. Tex. Aug. 22, 2008)	13
<i>Ferring B.V. v. Watson Labs, Inc.</i> , 764 F.3d 1382 (Fed. Cir. 2014).....	24
<i>Hakim v. Cannon Avent Grp.</i> , 479 F.3d 1313 (Fed. Cir. 2007).....	22
<i>Hamilton Products, Inc. v. O'Neill</i> , 492 F. Supp. 2d 1328 (M.D. Fla. 2007)	25
<i>Input/Output, Inc. v. Sercel, Inc.</i> , No. CIV.A. 5:06-CV-236, 2008 WL 5427982 (E.D. Tex. Apr. 28, 2008).....	26
<i>Interval Licensing LLC v. AOL, Inc.</i> , 766 F.3d 1364 (Fed. Cir. 2014).....	15

<i>KLA-Tencor Corp. v. Xitronix Corp.</i> , No. A-08-CA-723-SS, 2011 WL 318123 (W.D. Tex. Jan. 31, 2011).....	26
<i>Koepnick Med. & Educ. Research Found., L.L.C. v. Alcon Labs., Inc.</i> , 347 F. Supp. 2d 731 (D. Az. 2004)	23
<i>Kraft Foods, Inc. v. Int’l Trading Co.</i> , 203 F.3d 1362 (Fed. Cir. 2000).....	9, 14
<i>Med. Research Inst. v. Bio-Engineered Supplements & Nutrition, Inc.</i> , No. 605 CV 417, 2007 WL 128937 (E.D. Tex. Jan. 12, 2007)	28
<i>Merck & Co v. Teva Pharms. USA, Inc.</i> , 395 F.3d 1364 (Fed. Cir. 2005)	24, 30
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 134 S.Ct. 2120 (2014)	10
<i>Nike Inc. v. Wolverine World Wide, Inc.</i> , 43 F.3d 644 (Fed. Cir. 1994).....	10
<i>Omega Eng’g, Inc. v. Raytek Corp.</i> , 334 F.3d 1314 (Fed. Cir. 2003)	18
<i>Pentair Water Pool and Spa, Inc. v. Hayward Industries, Inc.</i> , 2012 WL 6608619 (E.D. N.C. Dec. 18, 2012).....	4
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	29
<i>Renishaw PLC v. Marposs Socita Per Azioni</i> , 158 F.3d 1243 (Fed. Cir. 1998).....	10
<i>S.O.I.Tec Silicon On Insulator Technologies, S.A. v. MEMC Electronic Materials, Inc.</i> , No. 08-292, 2010 WL 4025580 (D. Del. Oct. 13, 2010).....	26
<i>Secor View Techs. LLC v. Nissan N. Am., Inc.</i> , No. CIV. 12-3306 FSH, 2013 WL 6147788 (D.N.J. Nov. 21, 2013).....	26
<i>SkinMedica, Inc. v. Histogen Inc.</i> , 727 F.3d 1187 (Fed. Cir. 2013)	7, 12, 14
<i>Southwall Techs. v. Cardinal IG Co.</i> , 54 F.3d 1570 (Fed. Cir. 1995)	18
<i>Standard Oil Co. v. Am. Cyanamid Co.</i> , 774 F.2d 448 (Fed Cir. 1985).....	25
<i>Synthes (USA) v. Smith & Nephew, Inc.</i> , 547 F. Supp. 2d 436 (E.D. Pa. 2008).....	25, 27
<i>Takeda Pharm. Co. Ltd. v. Actavis Labs. FL, Inc.</i> , No. CV 15-451-RGA, 2016 WL 3193188 (D. Del. June 6, 2016).....	28
<i>Teva Pharm. USA, Inc. v. Sandoz, Inc.</i> , 789 F.3d 1335 (Fed. Cir. 2015)	13
<i>Thorner v. Sony Computer Entm’t Am. LLC</i> , No. 2011-1114, 2012 WL 280657 (Fed. Cir. Feb. 1, 2012).....	18
<i>Tobinick v. Olmarker</i> , 753 F.3d 1220 (Fed. Cir. 2014)	28
<i>TorPharm Inc. v. Ranbaxy Pharm., Inc.</i> , 336 F.3d 1322 (Fed. Cir. 2003)	23

STATUTES

35 U.S.C. § 102(e)	24
35 U.S.C. §311(b)	4

TABLE OF ABBREVIATIONS

Allergan	Allergan Inc.
Defendants	Teva Pharmaceuticals USA, Inc. Akorn, Inc. Mylan Pharmaceuticals Inc. Mylan Inc. Innopharma, Inc. Famy Care Limited
The asserted patents	U.S. Patent 8,629,111 (ECF No. 155-1); U.S. Patent 8,633,162 (ECF No. 155-2); U.S. Patent 8,642,556 (ECF No. 155-3); U.S. Patent 8,648,048 (ECF No. 155-4); U.S. Patent 8,685,930 (ECF No. 155-5); U.S. Patent 9,248,191 (ECF No. 155-6).
Calman Dec.	Declaration of Dr. Calman
Calman Tr.	Deposition of Dr. Calman
Noecker Dec.	Declaration of Dr. Noecker (ECF No. 155-35)
Noecker Tr.	Deposition of Dr. Noecker
Calman Tr.	Deposition of Dr. Calman
Xia Dec.	Declaration of Dr. Xia
Xia Tr.	Deposition of Xia (ECF. No. 155-20)
IPR	<i>Inter Partes</i> review
POSA	Person of ordinary skill in the art

Note: all emphasis added throughout unless otherwise indicated.

I. Introduction

The patents-in-suit suffer ambiguities and deficiencies from which there is no cure. Rather than acknowledge the lack of clarity in the asserted patents, Allergan instead claims that Defendants take a “see-what-sticks” approach in asserting that the majority of terms in dispute are indefinite. In reality, it is *Allergan* who asserts *all one hundred fifty-seven* claims from *six* patents to see what sticks in this litigation: as Allergan acknowledged in the prosecution history, the patents-in-suit are not novel or innovative. Rather, the patents—which are all directed to the same ophthalmic emulsion formulation—simply reiterate the formulation disclosed in the prior art Ding patent.

Despite Allergan’s extensive discussion of Ding in its opening brief, Allergan fails to tell the Court that the formulation for Restasis, the alleged embodying product, has not changed since Allergan listed Ding in the Orange Book as claiming the Restasis product. Instead, Allergan hangs its hat on alleged unexpected results of a formulation containing specific ratios of cyclosporin and castor oil, the *same* ingredients disclosed in Ding, which has since expired. Either Ding covers the Restasis product—as Allergan asserted in listing Ding in the Orange Book—or it doesn’t—as Allergan claims in its opening brief. But Allergan cannot have it both ways.

Allergan’s pattern of asserting inconsistent positions does not end there. For example, Allergan’s proposed constructions contradict not only the claims, specifications, and prosecution history of the asserted patents, but also undermine the very positions it tries to assert. Allergan ignores the doctrine of claim differentiation, as well as its own proposed constructions, in a poorly veiled attempt to broaden the FDA-approved indication for Restasis so that Defendants’ ANDA products are ensnared by an improperly broadened scope of the patents-in-suit. Allergan alleges, despite expert opinion, that all dry eye is caused by inflammation in a weak attempt to not only broaden the use of Restasis to all dry eye conditions—as opposed to only

keratoconjunctivitis sicca, for which Restasis is approved—but to also improperly broaden the scope of the claims for purposes of infringement. Allergan’s positions are scientifically wrong and meritless.

In contrast, the intrinsic record, as well as expert testimony, supports Defendants’ indefiniteness positions and proposed constructions. Defendants respectfully request that the Court adopt Defendants’ positions and find the claims of the patents-in-suit invalid as indefinite.

II. Dry Eye, Dry Eye Disease, Dry Eye Syndrome, Keratoconjunctivitis Sicca

Claim Term	Allergan’s Construction	Defendants’ Construction
dry eye / dry eye [disease/syndrome]	A group of disorders of the tear film, including those caused by reduced tear production or tear evaporation or an imbalance of tear film components associated with clinical signs, ocular discomfort and/or visual symptoms	Indefinite
keratoconjunctivitis sicca	A subset of dry eye disease, characterized by inflammation of the conjunctiva and of the cornea, associated with decreased tears	Indefinite

The terms dry eye, dry eye disease, dry eye syndrome, and keratoconjunctivitis sicca, as used in the claims, are not readily understood by a POSA. Each of these terms has been defined in a multitude of different ways, a phenomenon recognized by those in the industry and in the scientific literature. Faced with the task of trying to discern the particular meaning of the dry eye terms¹ and keratoconjunctivitis sicca (“KCS”), a POSA would look to the claims, specification, and prosecution history for guidance, only to find none. Accordingly, the dry eye terms are indefinite. *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620, 630 (Fed. Cir. 2015), *aff’d* 458 F. App’x 910 (Fed. Cir. 2012) (“the patent [] must ... establish that, where multiple known approaches exist, a person having ordinary skill in the art would know which approach to select ... the claims, when read in the light of the specification and prosecution history, must provide objective boundaries for those of skill in the art.”) (quotations omitted).

¹ For ease of reference, “dry eye terms” refers to the sum of the terms “dry eye,” “dry eye disease,” and “dry eye syndrome.”

Not only does the intrinsic record fail to provide a POSA with guidance of the scope of the asserted patents with reasonable certainty, Allergan further muddies the waters by: relying on prior art references not properly incorporated by reference into the specification; erroneously contending that all signs and symptoms of dry eye and KCS are ultimately caused by inflammation; and proposing constructions that are inconsistent with its other proposed constructions, the intrinsic record, and the presumption of claim differentiation.

A. The Dry Eye Terms Are Used Colloquially and Refer to a Number of Different Causes

Use of the terms dry eye, dry eye disease, dry eye syndrome, and KCS has been murky and inconsistent at best, and self-contradictory at worst. Ex. 24, Calman Dec. ¶ 21; *see also* Noecker Dec., Ex. M at 645 (“there has been considerable confusion regarding the definition of dry eye as well as the diagnostic classification of dry eye conditions”). These terms have been used both interchangeably with, and distinctly from, each other, and have been given multiple meanings, or been proposed to be dropped altogether. Calman Dec. ¶ 21, 24-30.

Problematically, “dry eye” is generally used as a colloquial, catch-all term for a common set of symptoms causing individuals to seek ophthalmic care, such as sensations of dryness, itching or irritation, and/or clinical findings that indicate a deficient or unstable tear film. Calman Dec. ¶ 20. “Dry eye” signs and symptoms can be caused by a multitude of disparate underlying conditions and factors, loosely divided into two main categories: aqueous deficient dry eye and evaporative dry eye.² Calman Dec. ¶¶ 20-23, 32-39, 54-61. Aqueous deficient dry eye and evaporative dry eye, in turn, may result from a number of different pathways or causes. *Id.*; *see also* Ex. 1, Noecker Tr. at 116-123.

² Failure to secrete enough tears is known as aqueous-deficient dry eye and excessive evaporation of tears is known as evaporative dry eye.

However, the colloquial use of the term “dry eye” fails to particularly point out which of the many possible underlying etiologies of “dry eye” cause a patient’s complaint. Allergan has admitted that an understanding of the root cause of a patient’s dry eye is crucial for utilizing the claimed invention. Opening Br. at 14-15. Similarly, persons of skill in the art have emphasized the need to avoid the historically sloppy and imprecise “dry eye” terminology—including the dry eye terms and “KCS”—and instead use terminology more precisely identifying the underlying cause(s) of the patient’s “dry eye.” Calman Dec. ¶¶ 22, 24. Thus, the dry eye terms and KCS do not have a clear or plain meaning in the ophthalmic community.

Allergan attempts to overcome this well-known ambiguity by erroneously asserting that Defendants’ experts, including Mylan’s IPR expert, have agreed with Allergan’s proposed constructions. Opening Br. at 19-20. Allergan’s attempts are misguided. First, both Mylan and Dr. Xia discussed the dry eye terms in the context of an IPR proceeding where: (1) a petitioner is not allowed to argue indefiniteness, 35 U.S.C. §311(b) (“[a] petitioner in an [IPR] may request to cancel as unpatentable ... claims of a patent *only* [] under section 102 or 103”), and (2) the USPTO applies the “broadest reasonable interpretation” claim construction standard, rather than the much narrower standard applied by the courts. *Pentair Water Pool & Spa, Inc. v. Hayward Indus., Inc.*, No. 5:11-cv-459-D, 2012 WL 6608619, at *3 (E.D. N.C. Dec. 18, 2012) (holding that because of, *inter alia*, the difference in claim construction standards, determinations in USPTO proceedings offer limited guidance for a district court). Thus, opinions rendered in the IPR proceedings are not germane to the indefiniteness inquiry here.

Second, Dr. Calman qualified that his construction is simply a particular, nonspecific definition that he personally uses in certain clinical settings, and not the only definition, of which there are many. Ex. 2, Calman Tr. at 14:10 – 15:10, 18:16 – 20:18 (“[T]his case obviously is not

about Andy's preferred definition for dry eye. ... I think it would be arrogant of me to say that this is the correct definition or the only definition, when there are so many learned people out there writing different definitions."'). Accordingly, Dr. Calman's testimony *supports* Defendants' indefiniteness position. *Dow Chem.*, 803 F.3d at 635 ("a claim term is indefinite if it 'leave[s] the skilled artisan to consult the unpredictable vagaries of any one person's opinion'") (citation omitted).

B. The Intrinsic Record Provides No Clarification as to the Meaning or Causes of Dry Eye, Dry Eye Disease, Dry Eye Syndrome or KCS

A POSA would appreciate the different underlying causes of dry eye and KCS referred to in the claims, as well as the inconsistent use of these terms by the ophthalmic community, and would therefore look to the patent specifications for guidance, only to find no help. The patentees use the imprecise terminology of dry eye, dry eye disease, dry eye syndrome, and KCS in different claims across all patents without any attempt in the intrinsic record to adequately define or differentiate between them. *Compare* '111 patent, claim 21 ("...treating keratoconjunctivitis sicca") *with* '111 patent, claim 23 ("...treating dry eye") *and* '162 patent, claim 21 ("...treating dry eye syndrome") *and* '162 patent, claim 22 ("...treating dry eye disease").

Nor do the specifications refer to a specific, underlying cause of any of the afflictions. The '111, '930, and '048 patents contain a common paragraph³ that uses each of the terms dry eye disease, dry eye syndrome, and KCS in a manner that further confuses the meaning of each term:

The present methods are useful in treating any suitable condition which is therapeutically sensitive to or treatable with cyclosporin components. Such conditions preferably are ophthalmic or ocular conditions[]. Included among such conditions are, without limitation, **dry eye syndrome**, ... **atopic keratoconjunctivitis**, ... and the like conditions. The present invention is particularly effective in treating **dry eye syndrome**. Cyclosporin has been found effective in treating **immune mediated keratoconjunctivitis sicca (KCS or dry eye disease)** in a patient suffering therefrom ... Other conditions that can be treated with cyclosporin components include an absolute or partial **deficiency in**

³ The asserted patents share a common specification with the exception of one substantive paragraph. Noecker Tr. at 52:11-13.

aqueous tear production (keratoconjunctivitis sicca or KCS) ... The treatment can further serve to correct corneal and conjunctival disorders exacerbated by tear deficiency and **KCS**, such as corneal scarring, corneal ulceration, inflammation of the cornea or conjunctiva, filamentary keratitis, mucopurulent discharge and vascularization of the cornea.

'111 patent, 2:55 – 3:11. Here, a POSA would not only fail to find any actual definition of the dry eye terms or KCS, but would also be left wondering whether the patentees understood these terms themselves. This is the only portion of the specification that refers to KCS and dry eye disease, but it inconsistently uses the terms synonymously, *id.* at 2:66 (“(KCS or dry eye disease)”), then subsequently offers a completely unique definition of KCS, *id.* at 3:3-5 (“an absolute or partial deficiency in aqueous tear production (keratoconjunctivitis sicca or KCS)”). Indeed, it is unclear whether KCS is a synonym for “deficiency in aqueous tear production,” *id.*, or a separate entity distinct from aqueous tear deficiency. *Id.* at 3:6-8.

Moreover, the portion of the specification cited above uses the dry eye terms and KCS contrary to the general understanding of those of ordinary skill in the art. For example, the specification notes the alleged invention is effective to treat dry eye conditions caused by inflammation or decreased lacrimal tearing, including “immune mediated keratoconjunctivitis sicca (**KCS or dry eye disease**).” '111 patent, 2:65 – 3:2. However, this attempt to equate “KCS” and “dry eye disease” is inconsistent with the medical literature, much of which reflects inconsistent usage of these terms. Calman Dec. ¶¶ 15, 25, 37, 48. And, unlike “immune mediated keratoconjunctivitis sicca,” a POSA as of 2003 would understand “dry eye disease” or “dry eye syndrome” to include a myriad of conditions, some of which do not involve decreased lacrimal tearing due to inflammation. Calman Dec. ¶¶ 36, 39, 54-59 (*e.g.*, Vitamin A deficiency, eyelid deformity, Meibomian gland dysfunction, staring, etc.).

The remainder of the specification does nothing to remedy these deficiencies. It makes no further attempt to define or clarify the various dry eye and KCS terms, instead simply

referencing “dry eye syndrome,” “dry eye,” and “dry eye disease” seemingly interchangeably without comment.

C. Allergan Erroneously Relies on Prior Art References Not Incorporated By Reference To Support its Proposed Construction

Allergan’s allegation that its construction of the dry eye terms is consistent with the “intrinsic record” is unavailing. Opening Br. at 19-20. First, as discussed above, the intrinsic record does not offer an actual definition of the dry eye terms. Tellingly, Allergan does not dispute the fact that the intrinsic record does not offer any definition or guidance.

Instead, Allergan points to a definition of “dry eye” set forth in a prior art publication—Sall—that the patents allegedly incorporate by reference. Opening Br. at 19-20. However, nowhere in the specification are the particular portions of Sall or any other cited publication “identif[ied] with detailed particularity” to be properly incorporated by reference *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1207 (Fed. Cir. 2013). Additionally, Sall itself problematically defines “dry eye” in terms of symptomology rather than the underlying cause of the patient’s signs and symptoms, which contravenes Allergan’s argument that understanding the underlying cause of a patient’s disease state is essential for practicing the underlying invention. *See* Opening Br. at 14-15, 19-20; *see also* Noecker Tr. at 103:20 – 104:5. Moreover, the references cited within Sall offer definitions of “dry eye disease” that differ not only from Sall’s proffered definition, but also from one another.⁴ ECF No. 155-7.

⁴ Exs. 3-6 (defining “dry eye” as, *inter alia*: KCS typically associated with Sjogren’s syndrome; KCS due to either atrophy of the lacrimal gland or atrophy secondary to Sjogren’s syndrome; tear volume deficiency associated mainly with Sjogren’s syndrome; tear film abnormalities arising from a broad range of causes; the presence of various common signs and symptoms caused by tear deficiency and/or evaporative issues).

D. Allergan's Proposed Constructions Fail Because All Signs And Symptoms of "Dry Eye" And "KCS" Are Not Ultimately Caused by Inflammation

Allergan has attempted to overcome the deficiencies in the intrinsic record by asserting that all "dry eye" and "KCS" signs and symptoms ultimately have one single underlying cause: inflammation. Opening Br. at 14; Noecker Dec. at ¶¶ 18, 24. Allergan is incorrect. A POSA as of 2003 would have understood that signs and symptoms of "dry eye" can be a manifestation of a large variety of underlying causes, many of which do **not** involve inflammation, such as Vitamin A deficiency, hereditary neurologic conditions, side effects of systemic drugs, as well as many types of evaporative dry eye where aqueous tear production is already normal. Calman Dec. ¶¶ 36, 39, 54-59. Even if the medical community "later understood" that all manifestations of "dry eye" have at least an inflammatory component,⁵ Noecker Dec. ¶ 18, Allergan's arguments are internally inconsistent.

For example, in discussing the efficacy terms (*infra*), Allergan repeatedly emphasizes the need to distinguish treatment of the underlying disease causing dry eye from palliative care for the symptoms of dry eye. Opening Br. at 14-18. Yet, as to the dry eye terms and KCS, Allergan erroneously conflates inflammation as a component of a patient's dry eye, which may be considered a "secondary consequence" of increased evaporation, Calman Dec. ¶¶ 27, 59, with inflammation as the inciting cause of the patient's dry eye, as in aqueous deficient KCS – a fact that Allergan's own expert later admits. *Compare* Noecker Dec. ¶ 18 ("dry eye was caused by an inflammatory process"); *with* Noecker Tr. at 78:18-23 ("inflammation is [] what you get to.

⁵ Despite Dr. Noecker's assertions, this supposed "later understanding" does not actually enjoy a consensus in the medical community. Calman Dec. ¶¶ 24-30, 54-60. Moreover, assuming *arguendo* that inflammation was recognized to be a component of all non-aqueous deficient types of dry eye in 2003, ocular surface inflammation was generally considered a secondary consequence, rather than an underlying cause. *Id.*

... I'm not going to say it's the [] underlying condition"). Allergan's proposed constructions for the dry eye terms and "KCS" are thus inconsistent with its rhetoric and the opinions of its expert.

E. Allergan's Proposed Constructions are Inconsistent with Its Other Proposals, the Intrinsic Record, and the Presumption of Claim Differentiation

It is apparent that even Allergan does not know what the dry eye terms and KCS mean. Allergan incongruously asserts that (1) KCS is a subset of dry eye disease, Opening Br. at 19 ("Keratoconjunctivitis sicca is a subset of dry eye disease"); and (2) KCS and dry eye are synonymous. Opening Br. at 14 ("Restasis is the first ophthalmic emulsion that treats dry eye or KCS"); Noecker Tr. at 127:6-7 ("KCS and dry eye are kind of the same thing"); *see also e.g.*, '111 patent, 2:65-66 ("[c]yclosporin has been found as effective in treating immune mediated keratoconjunctivitis sicca (KCS or dry eye disease)"). Additionally, "dry eye," "dry eye disease," and "dry eye syndrome" are present in separate claims and therefore have separate meanings—a fact that Allergan admits. Opening Br. at 20. But Allergan also admits that "dry eye," "dry eye disease," and "dry eye syndrome" all mean exactly the same thing. *Id.* at 19; *see also* Noecker Tr. at 28:1-5. Thus, Allergan's proposed construction renders *multiple* claim terms superfluous, in contravention of the doctrine of claim differentiation. *See Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366-69 (Fed. Cir. 2000) (claims are presumed to have different scope when different words or phrases are used in those claims).

Allergan also asserts that its Restasis product, which is only approved to treat inflammation "presumed to be caused by KCS," embodies each of the asserted claims, even those covering "dry eye," "dry eye disease," and "dry eye syndrome." Opening Br. at 14; Noecker Dec. ¶¶ 22-23. Allergan cannot, and does not, explain how these inconsistent and directly contradictory contentions can all be true. Rather, Allergan proposes constructions for the dry eye and KCS terms in a thinly veiled attempt to broaden the scope of the claims to read on Defendants' ANDA

products. *Nike Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 647 (Fed. Cir. 1994) (holding that a patentee “cannot, in effect, rewrite its patent claims to suit its needs in this litigation”).

In light of the confusing and oftentimes contradictory uses of the “dry eye” terminology in the industry and literature, as well as the complete lack of guidance from the intrinsic record, a POSA would not understand which of the many possible definitions of “dry eye,” “dry eye disease,” “dry eye syndrome” and “KCS” fall within the scope of the claims. Accordingly, the claims reciting “dry eye,” “dry eye disease,” “dry eye syndrome,” and “KCS” are indefinite. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2130 n.8 (2014) (a claim is indefinite where its language “might mean several different things” and the patent itself identifies “no informed and confident choice ... among the contending definitions”) (citation omitted); *cf.* *Renishaw PLC v. Marposs Socita Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (a claim is definite “[w]here there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meaning.”).

III. Efficacy

Claim Term	Allergan’s Construction	Defendants’ Construction
effective amount in treating [<i>keratoconjunctivitis sicca</i> / <i>dry eye</i>]	Plain and ordinary meaning, which is: An amount effective to treat the underlying disease.	Indefinite
effective in treating [<i>keratoconjunctivitis sicca</i> / <i>dry eye</i> / <i>dry eye disease</i>] therapeutically effective / therapeutically effective in treating [<i>dry eye</i> / <i>dry eye disease</i> / <i>keratoconjunctivitis sicca</i>]	Plain and ordinary meaning, which is: Effective in treating the underlying disease.	Indefinite
therapeutic effectiveness therapeutic efficacy	Plain and ordinary meaning, which is: Effectiveness / Efficacy in treating the underlying disease.	Indefinite
overall efficacy substantially equal to; as substantially therapeutically effective as a second emulsion achieves at least as much therapeutic effectiveness / efficacy	Substantially equal efficacy in treating the underlying disease; Substantially as effective in treating the underlying disease as a second emulsion / achieves at least as much effectiveness [efficacy] in treating the underlying disease	Indefinite

The issue with the efficacy terms is not that they fail to distinguish between treating the underlying disease versus providing temporary palliative relief of the disease symptoms, as Allergan's argues. *See* Opening Br. at 15. Rather, the issue here is that the asserted patents—and Allergan's proposals—fail to state the precise underlying disease to be treated.

A. Allergan's Proposed Constructions Fail to Identify the "Underlying Disease" to Be Treated

Allergan argues that the claimed invention must have efficacy in "treating the underlying disease." Opening Br. at 14. Yet, as described above, due to the patentees' imprecise and haphazard use of the dry eye terms and KCS within the claims and specification, a POSA would not know which of the underlying causes of dry eye, dry eye disease, dry eye syndrome, or KCS are to be treated using the alleged invention. To determine efficacy, a POSA must be able to identify the underlying disease requiring treatment. Calman Dec. ¶¶ 32-35, 53-61. However, as explained above, there are multiple causes of dry eye and KCS; therefore a POSA would not be able to pinpoint the underlying disease to be treated, and would not understand with a reasonable certainty the metes and bounds of the asserted claims. *Id.* Accordingly, the efficacy terms are indefinite. *See Andrulis Pharms. Corp. v. Celgene Corp.*, C.A. No. 13-1644-RGA, 2015 WL 3978578, at *6 (D. Del. Jun. 26, 2015), *aff'd* No. 2015-1962, 2016 WL 3755929 (Fed. Cir. July 14, 2016) (per curiam) ("enhanced therapeutically-effective amounts of thalidomide" held indefinite because there were multiple meanings of "enhanced" and the patentee did not clarify which meaning controlled).

Again, Allergan's proposed constructions introduce *additional* ambiguity. Allergan makes much of the fact that the claimed invention must be effective to treat the underlying disease, which it contends is inflammation of the ocular surface, including the cornea and conjunctiva. Opening Br. at 15. However, as discussed in Dr. Calman's declaration and as

conceded by Allergan's expert, Dr. Noecker, the "underlying disease" of inflammation can be either a secondary effect or an underlying cause of a patient's "dry eye." Calman Dec. ¶¶ 27, 54-59; Noecker Tr. at 86:24 – 87:6 ("the neural stimulus for tear production gets compromised[,] [s]o then tear production decreases, the ocular surface is less protected and, therefore, gets more inflamed[] [a]nd then more inflammation leads to another level of decreased production and it keeps going around in a vicious circle."). Dr. Noecker's assertions that inflammation is part of a "vicious circle" introduces further confusion by failing to discriminate between inflammation as an underlying cause (as in immune-mediated aqueous deficient conditions) versus inflammation as a secondary effect (as in most other dry eye conditions).

B. The Patents Fail to Disclose the Particular Methods Used to Determine Whether the Metes and Bounds of the Efficacy Claims Have Been Met

Allergan's assertion that the patents incorporate "well known methods used by clinicians for determining whether an emulsion is effective in treating the underlying disease" is misleading. Opening Br. at 17 (citing Sall). As discussed above, no portion of the Sall paper was "identif[ied] with detailed particularity." Therefore any alleged "objective measures of clinical efficacy" mentioned in Sall, *e.g.*, Schirmer tear testing and corneal staining, were not incorporated by reference into the specification. *SkinMedica*, 727 F.3d at 1207. Nor are these test methods disclosed in the asserted claims or specifications.

Additionally, there are many different methods used by clinicians to evaluate a patient's "dry eye," but the specific methods and standards a clinician should use largely depends upon the underlying cause of the patient's "dry eye." Calman Dec. ¶¶ 33-35, 52-60 (*e.g.*, Schirmer testing, tear break-up time, corneal staining, tear osmolarity, slit lamp examination, and impression cytology); *see also* Noecker Tr. at 132:18-24. Problematically, the patents fail to describe the specific causes of dry eye conditions and/or KCS the alleged inventions are intended to treat. The patents also fail to discuss

which of the myriad of methods and standards a POSA should use to assess the claimed efficacy. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344-45 (Fed. Cir. 2015) (holding “molecular weight” indefinite because it could be measured in at least three different ways, did not have a single plain meaning to one of skill in the art, and was used inconsistently).

In sum, neither the patents nor Allergan’s proposed constructions provide any guidance as to the root cause of the “underlying disease” to be treated by the claimed ophthalmic emulsions.⁶ A POSA would therefore have little to no context to determine which methods and standards a clinician should use to determine whether the claimed ophthalmic emulsion is “effective in treating the underlying disease.”

IV. Enhancing and Restoring

Claim Term	Allergan’s Construction	Defendants’ Construction
enhancing/restoring tearing	Plain and ordinary meaning	Indefinite
enhancing/restoring lacrimal gland tearing	Plain and ordinary meaning	Indefinite

In *Andrulis*, the Federal Circuit summarily affirmed that the term “enhanced” in a pharmaceutical patent was indefinite because it could mean any one of a number of measures, and the patentee failed to provide any guidance or reasonable certainty as to its meaning. *Andrulis*, 2015 WL 3978578, at *3-6. The same analysis applies in this case; Allergan’s brief only reinforces that “enhancing” and “restoring” are indefinite terms of degree.

Allergan argues that because other claims of the asserted patents refer to “increasing tear production,” the terms “enhance” and “restore” refer to not just an increase in the amount of tears but also an increase in the quality of a patient’s tears. Opening Br. at 21-22. Allergan, however, cannot point to a single sentence in the patents-in-suit to support its definition of

⁶ Moreover, Allergan simply repeats the word “effective in treating” or “effective amount in treating” to define the word “effective.” This approach is wholly unhelpful. *See Fenner Inc., Ltd. v. Microsoft Corp.*, No. 6:07 CV 8, 2008 WL 3981838, at *4 (E.D. Tex. Aug. 22, 2008).

enhancing or restoring because there is none. The common specification states only that cyclosporin is believed “to enhance or restore lacrimal gland tearing in providing the desired therapeutic effect,” ’191 patent, 9:12-16, and the extra paragraph simply adds that cyclosporin further acts “as an immunosuppressant.” ’111 patent, 2:67-3:2.

There is a good reason that Allergan concedes that the terms “enhancing” and “restoring” mean more than merely increasing the amount of tears; otherwise, the claims of the ’191 patent would impermissibly have the same scope as claims directed to increasing tear production. *See Kraft Foods*, 203 F.3d at 1366-69. The problem for Allergan is that the patents provide no guidance on what constitutes a qualitative or quantitative degree of enhancement or restoration.

Allergan cobbles together the teachings of Sall⁷ and the testimony of its expert, which rely on an analysis of Schirmer testing to measure volume of lacrimal gland tearing. *See* Opening Br. at 21-22; Noecker Dec. ¶ 42; Noecker Tr. 154:16-155:5; 159:21-162:7. But even this citation does not delineate what actually constitutes enhancing or restoring. The term “enhancing” suggests an increase in the amount of tears from some baseline level of production, which is fraught with unknowns. Calman Dec. ¶ 70 (“it is unclear to a person of ordinary skill whether eyes with normal tear production, which are ‘dry’ due to evaporative dry eye conditions, also experience this ‘enhancement’ of tear production.”). Similarly, the term “restoring” suggests an increase in the amount of tears from a zero or near-zero level of tear production, but a POSA would have no idea how much increase in tearing would occur as a result of using the alleged invention, or whether such increase would restore tear production to normal or some other level. *Id.* ¶¶ 70-71.

The same vagueness afflicts the qualitative degree of the claimed enhancement or restoration. Allergan’s expert asserted increased goblet size density suggested an improvement

⁷ As described above, specific portions of the Sall paper were not properly “identif[ied] with detailed particularity,” and are not incorporated by reference. *SkinMedica*, 727 F.3d at 1207.

in the quality of the tear film, Noecker Dec. ¶ 43, but he could not state what level of increase would indicate such improvement. Noecker Tr. 152:16-21; 153:16-23. He further testified that to determine whether tears are “made better” – which was his interpretation of the qualitative improvement referenced by “enhancing” and “restoring,” – one looks for “a [] kind of happier, more normal ocular surface.” *Id.* at 162:9-23; 142:17-24 (“[W]hen you enhance something, you make it kind of more and better” and “when you’re restoring it, you’re basically increasing it and making it better.”). This is untenable. Because the specification offers no indication, the skilled artisan is improperly left to consult the “unpredictable vagaries of any one person’s opinion.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371, 1374 (Fed. Cir. 2014) (“[s]uch ambiguity falls within the innovation-discouraging zone of uncertainty against which [the Supreme Court] has warned.”) (internal quotations omitted).

Nor can a POSA distinguish between “enhancing” and “restoring” as required by the separate claims. The patents use the terms interchangeably. Allergan also treats the terms as synonyms, arguing that they both mean increasing the amount of and the quality of tears. Even Allergan’s expert, Dr. Noecker, admitted that when he refers to “increased tearing,” he is referring to “enhanced tearing.” Noecker Tr. 154:10-12.

Finally, Allergan argues that the term “lacrimal gland tearing” is narrower than “tearing” because it encompasses only tearing from the lacrimal gland. Opening Br. at 21 n.7. But merely adding the phrase “lacrimal gland” in the dependent claims does not rescue the indefiniteness or claim differentiation problems of the terms “enhancing” or “restoring.” The dependent claims only specify *what* causes the tearing, but they do not say how much or how better that tearing is.

V. Second Topical Ophthalmic Emulsion

Claim Term	Allergan's Construction	Defendants' Construction
second topical ophthalmic emulsion	Plain and ordinary meaning	Indefinite

The phrase “second topical ophthalmic emulsion” is indefinite because it does not identify all of the components in the emulsion needed to measure relative therapeutic efficacy, a measurement required by the claims in which the phrase appears. Both the asserted patents and Allergan’s expert confirm that without knowing such excipient components, one cannot determine the relative efficacy of the emulsion. Because the relevant asserted claims require the overall efficacy of a “first” topical ophthalmic emulsion be “substantially equal” to that of a “second” emulsion, there is no practical way to determine the scope of the claims in the absence of any information between the compositional difference between the first and second emulsion.

As an example, claim 1 of the ’191 patent states:

A method of treating dry eye disease...topically administering to a human eye in need thereof a first topical ophthalmic emulsion...[that] comprises cyclosporine A in an amount of 0.05% by weight, **polysorbate 80, acrylate/C10-30 alkylacrylate cross-polymer**, water, and castor oil in an amount of about 1.25% by weight... (emphases added)

Wherein the method provides overall efficacy substantially equal to administration of a second topical ophthalmic emulsion...comprising cyclosporine A in an amount of about 0.1% by weight and castor oil in an amount of 1.25% by weight...

It is undisputed that the claims in question require a comparison between the relative therapeutic efficacies of the first and second emulsions. Opening Br. at 23. It is also undisputed that the phrase “second topical ophthalmic emulsion” may include unidentified excipients in the emulsion. *See* Opening Brief at 23 n.8. Additionally, a POSA would read “second topical ophthalmic emulsion” as including excipients other than castor oil. Calman Dec. ¶ 76; Calman Tr. at 177:22-25; 178:22-179:4; 191:17-25; 192:9-17.

Allergan appears to contend that the concentration of cyclosporine A is all that is necessary to make the required comparison. Opening Br. at 23. However, the asserted patents clearly disclose that efficacy also depends on the particular excipients in the emulsion. The patents state that the compositions “may include one or more other components in amounts effective to facilitate the usefulness and effectiveness of the present methods and/or the presently useful compositions,” and list multiple specific examples of each type of component. ’191 patent, at 10:3-5, 20-23, 37-43, 55-67; 12:4-12. Indeed, Composition II in the specification and the “first topic ophthalmic emulsion” in the claims include two of the specifically preferred excipients identified: polysorbate 80 and acrylate/C10-alkyl acrylate cross-polymer (Premulen®). *Id.* at 14:25-38; Calman Dec. ¶¶ 78-80. And Allergan’s own expert agreed excipients could be a “very big factor” and have a “big impact” for certain patients. Noecker Tr. at 172:11-16; 172:23-173:3; 173:5-12.

Allergan attempts to circumvent the clear teachings of its own patents and expert by arguing that the term “comprising” in the body of the claims does not require that the claims recite every excipient.⁸ Opening Br. at 23 n.8. However Allergan offers no argument as to how one could compare the efficacy of the two emulsions described by the claims without knowing all of the components in the second composition affecting efficacy. Indeed, the cases cited by Allergan support Defendants’ position. In *Alcon Research*, the Federal Circuit found no evidence in the record that changing excipients (or other variables) would render the claimed invention inoperable and thus reversed the district court’s non-enablement argument. *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189 (Fed. Cir. 2014). In contrast, the record

⁸ To the extent Allergan argues that the second emulsion should be construed as being identical to the first emulsion save for the concentration of cyclosporine A, there is no basis for including or excluding the other excipients identified in the specification. A POSA would not assume the two formulations are otherwise identical. Calman Tr. at 189:8-23.

here establishes the criticality of knowing the missing excipients. And *Medical Research Institute v. Bio-Engineered Supplements & Nutrition* is inapposite: it simply holds that the term “comprising” used within the body of the claim has no automatic meaning. See Opening Br. at 23 n. 8.

VI. About

Claim Term	Allergan’s Construction	Defendants’ Construction
about	Plain and ordinary meaning, which is: Approximately	Precisely the amount stated; Alternatively: Indefinite

A. “About” Should be Construed to Mean Precisely the Amount Recited or, Alternatively, is Indefinite

“About” should be construed to mean “precisely the amount claimed.” The intrinsic evidence demonstrates that the term “about” was inserted in an attempt to inappropriately broaden the weight amounts of the components making up the claimed emulsion. Through repeated express arguments in the prosecution history, in an effort to overcome the invalidating prior art, Allergan restricted its alleged invention to a composition with the *exact* amounts of cyclosporin, castor oil, and other excipients identified in the claims.

A claim term cannot be given its “plain and ordinary” meaning if “the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). Disavowal occurs when a patentee “unequivocally disavows a certain meaning” of a claim term. *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003). When such disavowal occurs, the claim term must be narrowed “congruent with the scope of the surrender.” *Id.* A patentee can disclaim subject matter and narrow the meaning of a term through statements made in either the patent specification or during prosecution. *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

1. Neither the Claims nor the Specification Clarify the Scope of “About”

Neither the claims nor the specification define or clarify the degree that “about” broadens the claimed amounts. Indeed, when the precise amounts 0.05% cyclosporin A and 1.25% castor oil were first claimed during prosecution of the parent ’857 application, the qualifier “about” was not used. *See* Ex. 7 at COE_JDG_PriorArt_0000207-211. The term “about” first appeared in 2013 amendments filed in the various applications branching out from the original application filed ten years prior. *See* Exs. 8-13. Nowhere is “about” defined nor its scope discussed in the patents’ common specification. Rather, the specification uses the term without explanation. For example, with respect to the amount of the hydrophobic component (which ultimately became castor oil), the patents state that:

The hydrophobic component preferably is present in the emulsion compositions in an amount greater than about 0.625% by weight. For example, the hydrophobic component may be present in an amount of up to about 1.0% by weight or about 1.5% by weight or more of the composition.

See, e.g., ’930 patent, 3:48-52; *see also id.* at 4:19-22 (pH), 9:67-10:4 (emulsifier), 11:7-12 (polyelectrolyte/emulsion stabilizing component), 11:35-38 (demulcent), 12:44-48 (viscosity modifiers). But, in the sole example provided in the patents-in-suit (Example 1), “Composition II” discloses a formulation having *exact* amounts. *See id.* at 13:47-59.

2. The Prosecution Histories Limit “About” to the Precise Amounts Claimed

Each of the asserted patents are continuations of Appl. Ser. No. 11/897,177 (“the ’177 application”), filed August 28, 2007, which is a continuation of Appl. Ser. No. 10/927,857 (“the ’857 application”), filed August 27, 2004, and claims the benefit of provisional application Ser. No. 60/503,137 (“the ’137 provisional application”), filed September 15, 2003. There is similarly no definition nor even a disclosure of “about” in any of these prior applications.

The claims of the parent '857 application were initially drawn to a composition containing a hydrophobic component and a cyclosporin component in an amount of less than 0.1% by weight, wherein the ratio between the two was less than 0.08. *See* Ex. 7, claim 21 at COE_JDG_PriorArt_0000209. A dependent claim further recited the hydrophobic component is present in an amount greater than 0.625% by weight of the composition. *See* Ex. 7, claim 26 at COE_JDG_PriorArt_0000209-10. These claims were rejected as obvious in light of Ding. *See* Ex. 14, Non-Final Rejection, Jan. 17, 2007 at COE_JDG_PriorArt_0000457-60. The Examiner cited Ding as disclosing an ophthalmic composition containing water, castor oil, and cyclosporin A in an amount of less than 0.1% by weight, with a ratio of cyclosporin A to castor oil of 0.08 by weight. *Id.* (citing Ding at Example 1D and 3:30-37). The Examiner found that it would have been obvious to increase the amount of castor oil in Ding's Example 1D to reduce the cyclosporin A to castor oil ratio to below 0.08. *Id.*

Allergan responded by amending claim 21 to specify castor oil and cyclosporin A and added claims 37 to 40 directed to Composition II (1.25% by weight of castor oil, 0.05% by weight of cyclosporin A, and a cyclosporin A to castor oil weight ratio of 0.04). *See* Ex. 15, Amend., Mar. 27, 2007 at COE_JDG_PriorArt_0000478-80). Allergan traversed the rejection over Ding by arguing that Composition II produced unexpected benefits over alternative formulations, such as the Composition I formulation of Example 1. *Id.* at COE_JDG_PriorArt_0000482-85.

In a July 2, 2007 Final Office Action, the Examiner maintained the rejections, stating that the claimed compositions could be "readily envisaged" based on Ding and that arriving at the claimed invention was a mere optimization. Ex. 16 at COE_JDG_PriorArt_0000505-510. Allergan responded by re-arguing surprising and unexpected results of Composition II (*see* Ex.

17, Amend., Aug. 27, 2007 at COE_JDG_PriorArt_0000527-530) and identified claims 37-40 as being “drawn to preferred specific embodiments comprising a single concentration of cyclosporin (0.05%) and/or castor oil (1.25%).” *See id.* at 531. Claims 37-40 recited specific amounts and did not use “about.” Allergan urged:

it was ***utterly unpredictable that the concentration of castor oil (1.25%)*** present in both Composition I and Composition II of the present specification would be substantially non-irritating in human eyes...

Id. at 528. Further distancing the claimed compositions from the prior art Ding reference, Allergan stated:

The clear teaching [of Ding] is that an optimal weight ratio is 0.8%. Thus, [Ding] teaches away from the present invention. Applicants note that the present claim limitations do not use the term “about” with respect to these limitations, and therefore there is no overlap with the exemplary compositions of Example 1.

Id. 529-30.

When these arguments failed, Allergan appealed, re-arguing surprising and unexpected results of Composition II. *See* Ex. 18, Appeal Brief, Jan. 15, 2008 at COE_JDG_PriorArt_0000565. Allergan withdrew its Appeal, and filed a Request for Continued Examination. In the Remarks of an accompanying amendment, Allergan acquiesced to the Examiner’s obviousness rejections based on Ding:

[I]t would have been obvious to modify examples 1A-1E of [] Ding [] to arrive at Composition II of the present application. The differences are insignificant.

* * *

The formulation of Composition II is ***squarely within the teaching of the Ding reference***, and the Office should disregard any statements by the applicants suggesting otherwise...

Ex. 19, Response, June 15, 2009 at AGN_RES0200036-37.⁹ Allergan ultimately abandoned the ’857 application, in favor of various continuing applications.

⁹ Allergan also made this disavowal in the parent ’177 application. *See* Ex.19, Response, June 15, 2009 at AGN_RES0200036-37.

The term “about” was first introduced throughout the claim sets in Preliminary Amendments filed in those continuing applications resulting in the asserted patents. *See, e.g.*, Ex. 12, App. No. 13/961,828, Preliminary Amend., Aug. 7, 2013 at COE_JDG_PriorArt_0004512.¹⁰ In its Remarks for the Preliminary Amendments, Allergan purported to retract the disclaimer made in the ’177 and ’857 applications. *Id.* at 4516. As an initial matter, Allergan’s attempted retraction fails for lack of adequate specificity because Allergan offered no explanation as to how the disclaimer applied to the claims of the applications for the asserted patents.¹¹ Moreover, Allergan again had to limit its new claims to precise amounts to obtain patentability.

Specifically, Allergan submitted multiple declarations, purporting to show unexpected therapeutic effects from the “specific combination” of components in Composition II. The declaration compared Composition II and Ding formulations, attesting that the “specific combination” of amounts of components in Composition II formulation were “critical” for “surprising and completely unexpected” results:

Taking the results of these studies together, it is clear that the ***specific combination*** of 0.05% by weight cyclosporin A with 1.25% by weight castor oil is ***surprisingly and unexpectedly critical*** for therapeutic effectiveness in the treatment of dry eye/keratoconjunctivitis sicca.

Ex. 20, Schiffman Dec., Oct. 11, 2013 at COE_JDG_PriorArt_0005016-18. Allergan offered another declarant who stated that:

Taking the results of these studies together, it is clear that the ***specific combination*** of 0.05% by weight cyclosporin A with 1.25% by weight castor oil is ***surprisingly critical*** for therapeutic effectiveness for the treatment of dry eye/keratoconjunctivitis sicca,

¹⁰ Allergan alleged that the limitations in the new claims could be found throughout the specification. However, no portion of the specification provided support for the broadened claim recitations. Defendants further contend that the arbitrary addition of “about” throughout the claims is a violation of the written description and enablement requirements.

¹¹ *See Hakim v. Cannon Avent Grp, PLC.*, 479 F.3d 1313, 1317-18 (Fed. Cir. 2007) (rescission of disclaimer ineffective where the prosecution history was not sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be re-visited).

Ex. 21, Attar Dec., Oct. 14, 2013 at COE_JDG_PriorArt_0005042-43. Allergan likewise argued that:

Taking the results of the studies and data presented [], it is clear that the ***specific combination*** of 0.05% by weight cyclosporin A with 1.25% by weight castor oil is surprisingly ***critical*** for therapeutic effectiveness in the treatment of dry eye or keratoconjunctivitis sicca.

Ex. 22, Amend., Dec. 5, 2013 at COE_JDG_PriorArt_0005010 (second emphasis in original); *see also id.* at 5006-11.

The Examiner found these arguments and evidence persuasive and allowed the claims on this basis. *See* Ex. 23, Notice of Allowance, Jan. 28, 2014 at COE_JDG_PriorArt_0005089-92 (“it is clear that the ***specific combination of 0.05% by weight cyclosporin A with 1.25% by weight castor oil is surprisingly critical for therapeutic effectiveness*** in the treatment of dry eye or keratoconjunctivitis sicca”) (emphases added). The Examiner repeated this basis for patentability for each of the patents-in-suit. None of Allergan’s arguments or the Examiner’s statements used the term “about,” or allowed for leeway from precise amounts that might achieve the same degree of results.

Allergan never disputed the Examiner’s conclusion that the precise formula of Composition II was *critical* for allowance, and the claims are properly limited to the Examiner’s interpretation. *See TorPharm Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1330 (Fed. Cir. 2003) (“in ascertaining the scope of an issued patent, the public is entitled to equate an inventor’s acquiescence to the examiner’s narrow view of patentable subject matter with abandonment of the rest.”); *Koepnick Med. & Educ. Research Found., L.L.C. v. Alcon Labs., Inc.*, 347 F. Supp. 2d 731 (D. Az. 2004). The prosecution history therefore demonstrates the precise nature of the claimed amounts and disavowal of any other amounts purported to be encompassed by the indiscriminately employed “about” qualifier.

In addition to its emphasis on the specific combination of amounts of cyclosporin A and castor oil, Allergan also made clear disclaimers with respect to the other weight amounts and pH range of the claimed formulation. During the prosecution of the '828 application, the applicants traversed a rejection under 35 U.S.C. § 102(e) in view of U.S. Patent Application No. 10/621,053 to Bakhit *et al.* by antedating the reference with a formulation report for Allergan Formulation No. 9054X, which allegedly was conceived and reduced to practice before Bakhit. Ex. 22 at COE_JDG_PriorArt_0005011, 5058-70. The inventors swore that the 9054X formulation was an embodiment of the invention as claimed in the '828 application, which “contains 0.05% cyclosporin A, 1.25% castor oil, 0.05% [acrylate/C 10-30 alkyl acrylate cross polymer], 2.2% glycerin, 1.0% polysorbate 80, water, and sodium hydroxide (a buffer) at a pH of 7.4.” *Id.* The Examiner then allowed the claims over Bakhit. *See, e.g.*, Ex. 23 at COE_JDG_PriorArt_0005092. Based on Allergan’s statements that the claims were commensurate with formulation 9054X, the claim term “about” is properly limited to all of the precise weight amounts and pH range as claimed.

3. Allergan’s Cases On “About” Do Not Apply

In *Merck & Co v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1369 (Fed. Cir. 2005) and *Ferring B.V. v. Watson Laboratories, Inc.*, 764 F.3d 1382 (Fed. Cir. 2014), the Federal Circuit held that “about” should be given its plain and ordinary meaning *unless* the patentee clearly redefines it in the intrinsic evidence. In both cases, “about” meant “approximately” because the intrinsic evidence did not redefine the term to mean a specific numerical amount. Similarly, in *Biopolymer Engineering, Inc. v. Immunocorp*, No. CIV. 05-2972 JNE/JJG, 2007 WL 4562592, at *10, 12 (D. Minn. Dec. 21, 2007), the court construed “about” by its ordinary

meaning because there was no “evidence that would provide a basis to specify” the deviation.¹²

None of Allergan’s cases involved a patentee’s attempt to broaden the claims by adding “about” to modify every claimed number, without support in the specification, ten years into prosecution. And none involved similar critical concessions and disavowals during prosecution.

B. In the Alternative, the Term “About” is Indefinite

To the extent that the Court holds that Allergan did not limit the claims to the precise amounts listed during prosecution, the term “about” is fatally indefinite. There is no guidance or standard in the intrinsic record to allow one of ordinary skill to determine with reasonable particularity the amounts of the claimed components.¹³ Indefiniteness often arises when words of degree, such as “about,” are used in a claim. *See, e.g., BJ Servs. Co. v. Halliburton Energy Servs.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003). “When a word of degree is used the district court must determine whether the patent’s specification provides some standard for measuring that degree.” *Exxon Research & Eng’g Co. v. U.S.*, 265 F.3d 1371, 1381 (Fed Cir. 2001). Where the specification provides no such standard, the claim is indefinite. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991) (“about” indefinite); *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 453 (Fed Cir. 1985) (“partially soluble” indefinite).¹⁴

¹² Allergan also cites to district court case, *Allergan Inc. v. Sandoz, Inc. et al.*, No. 6:11-cv-441, Dkt. No. 118, 2013 WL 139350 (E.D. Tex. Jan. 10, 2013) for the proposition that other courts have construed about as approximately. In the *Sandoz* case however, the parties did not dispute the meaning of “about.”

¹³ Contrary to Allergan’s assertions, Dr. Xia’s testimony during the ’111 IPR fully supports Defendants’ indefiniteness argument. Dr. Xia explained that he did not give any weight to the term “about” and instead focused on the specific concentrations recited in the claims, *i.e.*, he interpreted “about” to mean “precisely.” *See, e.g., Xia Tr.* at 165:13-16.

¹⁴ Courts have **routinely** found claims indefinite where, as here, a nebulous term of degree is recited in the claim, without guidance as to scope. *See Synthes (USA) v. Smith & Nephew, Inc.*, 547 F. Supp. 2d 436, 454-455 (E.D. Pa. 2008) (holding “less than about 2%” indefinite because the claimed percentage was an “essential feature” and the specification provided no guidance as to how much below 2% would qualify as “about 2%”); *Hamilton Prods., Inc. v. O’Neill*, 492 F. Supp. 2d 1328, 1340 (M.D. Fla. 2007) (“approximately” failed to “clearly circumscribe what is foreclosed from future enterprise”); *Cayenne Med., Inc. v. Medshape, Inc.*, No. 2:14-cv-0451, 2016

For example, in *Amgen*, under the stricter pre-*Nautilus* standard, the Federal Circuit affirmed the ruling that “at least about 160,000” was indefinite. 927 F.2d at 1217-1218. During prosecution of the asserted patent, the claims reciting activity of “at least 120,000” were rejected in light of prior art disclosing a product with an activity of 128,620. *Id.* In response, the applicant replaced the rejected claims with ones tracking previously allowed claims that recited “at least 160,000,” except the new claims added the modifier “about” (“at least *about* 160,000”). *Id.* The district court held the claims indefinite, noting that the addition of the word “about” improperly constituted an effort to recapture a mean activity between the rejected 120,000 and the previously allowed 160,000, without any guidance as to which activity value between the prior art value of 128,620 and 160,000 would constitute infringement. *Id.* at 1218. The Federal Circuit affirmed, holding that “[w]hen the meaning of claims is in doubt, especially when, as is the case here, there is close prior art, they are properly declared invalid.” *See id.*

As in *Amgen*, here, the qualifier “about” was inserted to vaguely create broad weight ranges when only specific values were disclosed. Moreover, as discussed above, the intrinsic evidence does not provide any guidance as to the scope of the term “about.” For example, the specification provides no guidance as to whether “about 1.25 wt%” of castor oil encompasses 1.251, 1.255, 1.3, 1.5, etc. There is no dividing line. Instead, the intrinsic record only supports *exactly* 1.25; especially in light of the fact that the applicants obtained claim allowance by purporting to show that the specific combination of Composition II was “critical” to the

WL 2606983, at *6 (D. Ariz. May 6, 2016); *Fairfield Indus., Inc. v. Wireless Seismic, Inc.*, 4:14-CV-2972, 2015 WL 1034275, at *15-16 (S.D. Tex. March 10, 2015); *KLA-Tencor Corp. v. Xitronix Corp.*, No. A-08-CA-723-SS, 2011 WL 318123, at *3 (W.D. Tex. Jan. 31, 2011); *Input/Output, Inc. v. Sercel, Inc.*, No. CIV.A. 5:06-CV-236, 2008 WL 5427982, at *26 (E.D. Tex. Apr. 28, 2008); *Secor View Techs. LLC v. Nissan N. Am., Inc.*, No. CIV. 12-3306 FSH, 2013 WL 6147788, at *4 (D.N.J. Nov. 21, 2013); *S.O.I.Tec Silicon On Insulator Technologies, S.A. v. MEMC Elec. Materials, Inc.*, No. 08-292, 2010 WL 4025580, at *14-15 (D. Del. Oct. 13, 2010).

invention. Ex. 25, Xia Dec. ¶¶ 50-51. If “about 1.25 wt%” were construed to mean, *e.g.*, “1.23 – 1.27 wt%,” this arbitrary range would lack written description, and thus would not be correct. *Bayer CropScience AG v. Dow AgroSciences LLC*, 728 F.3d 1324, 1330 (Fed. Cir. 2013) (a construction that exceeds the patent disclosure and leads to concerns of lack of written description is incorrect). The same case exists for every other claim term qualified late in the game by the term of degree, “about.” Accordingly, as with the terms of degree in the many other cases, a POSA could not reasonably discern the boundary between the “about” ranges and the prior art—or determine what compositions might infringe—rendering the term indefinite. *See Amgen*, 927 F.2d at 1218; *Synthes*, 547 F. Supp. 2d at 454-455; Xia Dec. ¶¶ 49-52.

VII. Administering

Claim Term	Allergan’s Construction	Defendants’ Construction
Administering to [the/an] eye of [a/the] human / administered to [an/the] eye of [a/the] human / administered to a human	Plain and ordinary meaning, the word administering meaning prescribing, dispensing, giving, or taking.	Plain and ordinary meaning, which is delivering into or onto [the/an] eye of [a/the] human / delivered into or onto [an/the] eye of [a/the] human / delivered into or onto an eye of a human.
administering to [the/an] eye of [a/the] human / administered to [the/an] eye of [a/the] human / administered to a human / administering an emulsion topically to the eye of a human	Plain and ordinary meaning, the word administering meaning prescribing, dispensing, giving, or taking.	Plain and ordinary meaning, which is delivering into or onto [the/an] eye of [a/the] human / delivered into or onto [the/an] eye of [a/the] human / delivered into or onto an eye of a human / delivering an emulsion topically into or onto the eye of a human.
administering to a human eye / administered to the human eye / administration of [a/the] second topical ophthalmic emulsion to a human eye	Plain and ordinary meaning, the word administering meaning prescribing, dispensing, giving, or taking.	Plain and ordinary meaning, which is delivering into or onto a human eye / delivered into or onto the human eye / delivery of [a/the] second topical ophthalmic emulsion into or onto a human eye.

Allergan’s construction of the “administer” terms is too broad and is divorced from the plain meaning of the term within the context of medicine and the intrinsic evidence. Allergan’s construction would expand the scope of the claims to cover, for example, physicians who merely write a prescription; pharmacists who merely “dispense” drugs; wholesalers who merely “give” drugs to retail pharmacies; or sales reps who merely “give” samples to physicians. Nothing in

the intrinsic or extrinsic evidence indicates such an unusual meaning of “administer.” The plain and ordinary meaning of “administer” to a POSA is “delivered into or onto the eye of a human.” Calman Dec. ¶¶ 83-89.

Context is critical when ascertaining the meaning of claim terms. And viewed in context, Allergan’s constructions make no sense. For example, many of the claims require “*topically* administering *to the eye*” See, e.g., ’162 patent, cl. 1; ’048 patent, cl. 1; ’191 patent, cl. 1. Applying the adverb “topically” to Allergan’s constructions demonstrates their inappropriateness. No one “topically” prescribes or “topically” dispenses a drug. It also makes no sense to prescribe “to the eye” or to dispense “to the eye.” It makes perfect sense, however, to “topically” deliver into or on “to the eye.” Many claims also require “administering . . . *twice a day*.” See, e.g., *id.* Again, Allergan’s constructions make no sense because only actual delivery into or onto the eye might happen twice a day. Finally, numerous claims require that the cyclosporine emulsion be “*effective*.” See, e.g., *id.* However, a cyclosporin A formulation cannot be “effective” unless it is actually delivered into or onto the eye.

The specification is consistent with the context of the asserted claims. The term “administer[]” is nearly always preceded by the term “topically,” followed by the phrase “to the eye,” or refers to multiple daily administrations, and at no point does the term refer to merely prescribing, dispensing, giving, or taking. See, e.g., ’048 patent, at 4:42-62.

Numerous courts have construed the term “administering” consistent with Famy Care’s constructions here.¹⁵ In fact, the Federal Circuit recently affirmed a construction that is nearly

¹⁵ See, e.g., *Tobinick v. Olmarker*, 753 F.3d 1220, 1224-25 (Fed. Cir. 2014) (“administered locally” means administered “directly to the site”); *Takeda Pharm. Co. Ltd. v. Actavis Labs. FL, Inc.*, No. CV 15-451-RGA, 2016 WL 3193188, at *3-4 (D. Del. June 6, 2016) (“administering” means “delivering into the body”); *Med. Research Inst. v. Bio-Engineered Supplements & Nutrition, Inc.*, No. 605 CV 417, 2007 WL 128937, at *7 (E.D. Tex. Jan. 12, 2007) (same);

identical to Famy Care’s construction. *Andrulis Pharms. v. Celgene Corp.*, No. 2015-1962, 2016 WL 3755929, at *1 (Fed. Cir. July 14, 2016), *aff’g Andrulis Pharm. Corp. v. Celgene Corp.*, No. CV 13-1644, 2015 WL 3978578, at *2-3 (D. Del. June 26, 2015) (“administering” means “delivering into or onto a [] body,” and not “to mete out”, which improperly covered the actions of “essentially anyone giving or handing the drug to a patient”).

Allergan primarily and inappropriately relies upon general purpose dictionary definitions to support its unusual construction. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (noting that the multiple dictionary definitions for a term will extend beyond the construction of the patent). Allergan also conveniently leaves out important portions of cited definitions that provide necessary context. For example, Allergan truncates the definition “to give or apply in a formal way” to leave out the contextual clause “administer the last rites.” Opening Br., Ex. 31. Similarly, Allergan truncates the definition “to mete out; dispense,” to leave out the contextual clause “administer justice.” *Id.* Religion and law are both very different contexts than medicine. And the many definitions in the appropriate medical context are consistent with Famy Care’s construction: e.g., “directly apply a [] drug to the body of a patient,” and “direct application of [a] drug [] to the body of a patient.” Calman Dec. ¶ 89.

VIII. Cyclosporin A is the Only Peptide Present

Claim Term	Allergan’s Construction	Defendants’ Construction
cyclosporin A is the only peptide present	Plain and ordinary meaning, which is: Cyclosporin A is the only peptide present.	Plain and ordinary meaning, which is no other peptides are present except for cyclosporin A, including but not limited to no cyclosporin A metabolites, derivatives, or impurities.

The term “cyclosporin A is the only peptide present” has a readily apparent plain and ordinary meaning. In short, “only” means “only.” Therefore, the Court should adopt Famy

AstraZeneca AB v. Hanmi USA, Inc., No. CIV.A. 11-760 JAP, 2012 WL 6203602, at *5-6 (D.N.J. Dec. 12, 2012), *aff’d*, 554 F. App’x 912 (Fed. Cir. 2013) (“administration” does not mean “prescription by a physician” or “dispensing”).

Care's construction, where "cyclosporin A is the only peptide present" means what it says: there are "no other peptides present except for cyclosporin A." There is nothing to suggest the patentees redefined "only" to have some unique meaning.

The specification explains that "[t]he term 'cyclosporin component' as used herein is intended to include any individual member of the cyclosporin group and derivatives thereof, as well as mixtures of two or more individual cyclosporins." '111 patent, 3:38-41. However, the term "cyclosporin component" does not appear in the claims. Instead, the claims cover a very specific cyclosporin, cyclosporin A, where cyclosporin A is the only peptide present. If the patentees wanted to claim a composition where cyclosporin A was not the only peptide present, they could have claimed a "cyclosporin component." Moreover, the specification explicitly describes "several other minor metabolites, cyclosporin B through I." '111 patent, 3:28-30. The patent clearly disclosed other peptides in addition to cyclosporin A, but did not claim those.

Allergan appears to argue that the patentees acted as their own lexicographer and redefined "only" to mean something different than "only." But the Federal Circuit has "repeatedly emphasized that the statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." *Merck*, 395 F.3d at 1370. Here, there is no clear intent to redefine the term "only" to mean something different from its plain meaning.

IX. Conclusion

For the foregoing reasons, Defendants respectfully request that the Court adopt Defendants' proposed constructions.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email on this the 5th day of August, 2016.

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